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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Paper No. 0504

Application Number: 10/041,770
Filing Date: January 08, 2002
Appellant(s): HU ET AL.

David W. Hibler
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief in Paper No. 16, filed on November 13, 2002.

(1) Real Party in Interest

A statement identifying the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

Appellant's brief includes a statement that there are no related appeals or interferences.

(3) Status of Claims

The statement of the status of the claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Invention

The summary of invention contained in the brief is correct.

(6) Issues

The appellant's statement of the issues in the brief is correct.

(7) Grouping of Claims

Appellant's brief includes a statement that the claims stand or fall together.

(8) Claims Appealed

The copy of the appealed claims contained in the Appendix to the brief is correct.

(9) Prior Art of Record

Adams et al, The thrombospondin type 1 repeat (TSR) superfamily: diverse proteins with related roles in neuronal development. Dev Dyn. 2000 Jun;218(2):280-99).

Bork et al. Powers and pitfalls in sequence analysis: the 70% hurdle. Genome Res. 2000 Apr;10(4):398-400.

Brenner et al. Errors in genome annotation. Trends Genet. 1999 Apr;15(4):132-3..

Broun et al. Catalytic plasticity of fatty acid modification enzymes underlying chemical diversity of plant lipids. Science. 1998 Nov 13;282(5392):1315-7.

Buchner et al, TSRC1, a widely expressed gene containing seven thrombospondin type I repeats. Gene. 2003 Mar 27;307:23-30.

Buchner et al. Mus musculus thrombospondin repeat protein 1 (Tsrc1) mRNA, complete cds. Acc# AY158701 and NM_019032.

Fahrenholz et al. Alpha-secretase activity of the disintegrin metalloprotease ADAM 10. Influences of domain structure. Ann N Y Acad Sci. 2000;920:215-22

Fujiwara et al. HUM510H03B Human placenta polyA+ (T Fujiwara) Homo sapiens cDNA. Acc#D78761.

Jasny et al The human genome. Science. 2001 Feb 16;291(5507):1153.

Letunic et al. Recent improvements to the SMART domain-based sequence annotation resource. Nucleic Acids Res. 2002 Jan 1;30(1):242-4.

Massova et al. Matrix metalloproteinases: structures, evolution, and diversification. FASEB J. 1998 Sep;12(12):1075-95

NCI-CGAP http://www.ncbi.nlm.nih.gov/ncicgap tt07h06.x1 NCI_CGAP_GC6 Homo sapiens cDNA clone IMAGE:2240125 3' similar to WP:F25H8.3 CE05729 Thrombospondin like. Acc#AI637480.

Smith et al. The challenges of genome sequence annotation or "the devil is in the details". Nat Biotechnol. 1997 Nov;15(12):1222-3.

Van de Loo et al. An oleate 12-hydroxylase from Ricinus communis L. is a fatty acyl desaturase homolog. Proc Natl Acad Sci U S A. 1995 Jul 18;92(15):6743-7.

Venter et al. The sequence of the human genome. Science. 2001 Feb 16;291(5507):1304-51.

Yu et al. Sequence 33 from Patent WO0198468. 27-Dec-2001 Alignment with SEQ ID NO: 2.

Yu et al. Proteases. US patent Application Publication US 2004/0023243 05-Feb-2004.

(10) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 101

Claims 1-6 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility.

The title and the specification (pg 21, lines 9-15) assert that the polypeptide encoded by the recited polynucleotide is as a protease. Although the specification discloses that the claimed

polynucleotides "encode a protein which shares structural similarities with animal proteases, and particularly matrix metalloproteases, zinc dependent metalloproteases, and the ADAMTS family of secreted proteases" (pg 2, lines 6-9), said disclosure of structural similarity does not constitute an assertion of function.

While the specification asserts that the claimed polynucleotides encode a protease, the claimed invention does not meet the utility requirements for the following reasons.

An assertion that the recited polynucleotides encode a protease is not an assertion of a specific and substantial utility. The family of proteases is a large and variable family of enzymes with a large number of variable substrates and the potentiality of being involved in many different cellular processes and diseases. The specification fails to assert a specific utility or function, as a protease, for the protein of SEQ ID NO: 2 because the specification fails to assert the substrates that said "protease" cleaves, the cellular processes mediated by said "protease", or the specific diseases involving said "protease". Without such knowledge, a skilled artisan would not know how to use the protein.

A utility for the protein encoded by SEQ ID NO: 1, as set forth by SEQ ID NO: 2, has not been established. There is no experimental evidence to support the assertion that the claimed polynucleotides encode a polypeptide having protease activity. Furthermore, a specific and substantial utility for the protein of SEQ ID NO: 2 cannot be deduced based on homology to proteins of known function, as the protein of SEQ ID NO: 2 does not have homology with any protein that has been demonstrated to have protease activity. Although Yu et al, 2002 teach a polynucleotide (SEQ ID NO: 33) that encodes a protein having 99.6% identity with SEQ ID NO: 2 herein, said protein of Yu et al was identified by electronic assembly (Yu et al, 2004 [0272]-

[0290] & Table 2) and has not been demonstrated to have protease activity. As argued by Appellants, the human TSRC1 protein of Buchner et al has 99% identity with residues 425-857 of the protein set forth by SEQ ID NO: 2. However, the function of said protein of Buchner et al is not known. Therefore, polynucleotides encoding the protein of SEQ ID NO: 2 have neither a specific and substantial utility, based on homology of SEQ ID NO: 2 to proteins of known function, or a well established utility based on experimental evidence.

The state of the art also precludes a deduction of a specific and substantial utility for the recited polynucleotides. The asserted function for the claimed polynucleotides has been determined solely on the basis of structural similarity (i.e. sequence homology). The state of the art clearly teaches the unpredictability of assigning function based on sequence homology and acknowledges that, small changes can drastically change function. Bork et al, 2000, Smith et al, 1997 and Brenner, 1999 are some of the references that describe the overall state of the art in regard to the unpredictability of annotating function. Bork et al teaches the pitfalls associated with comparative sequence analysis for predicting protein function because of known error margins for high-throughput computational methods. Bork et al also indicates that one of the causes of this inaccuracy is that the quality of data available is still insufficient, especially data relating to protein function. Furthermore, Bork et al teaches that protein function is context dependent, and both molecular and cellular aspects must be considered (pg 398). Smith et al. indicates that there are numerous cases in which proteins of very different functions are homologous (pg 1222, third col, last parg). In addition, Brenner teaches the difficulty of accurately inferring function from homology and clearly states that most homologs must have different molecular and cellular functions (pg 132, col 2, parg 2). Examples, of pitfalls

associated with comparative sequence analysis for predicting function, are shown by Broun et al, 1998 and Van de Loo et al, 1995. Van de Loo et al. teaches that polypeptides of approximately 67% homology to a desaturase from *Arabidopsis* where found to be hydroxylases, once tested for activity. Broun et al. teaches that as few as four amino acid substitutions can convert an oleate 12-desaturase into a hydrolase and as few as six amino acid substitutions can transform a hydrolase to a desaturase.

The specification also asserts that the utilities for SEQ ID NO: 1 are: in microarrays, or other assays, to screen genetic material from patients; identification of mutations associated with SEQ ID NO: 1; diagnostic assays; preparation of anti-sense oligonucleotides derived from SEQ ID NO: 1; hybridization assays; library screening; characterization of genomic clones; PCR; restriction fragment length polymorphism analysis; isolation of full-length cDNA; preparation of fusion proteins; preparation of antibodies; as therapeutics (page 8-16); analysis of protein evolution; and preparation of transgenic animals (page 17-19). Each of these utilities is an application that would apply to every member of a general class of materials, i.e. any polynucleotide or polypeptide, and/or is a use only for further research to determine a use for the polynucleotide of SEQ ID NO: 1 or the protein encoded thereby.

The specification fails to disclose sufficient information in regard to the biological significance or further characterization of the claimed polynucleotides, and the proteins encoded thereby, which would be necessary for an artisan to know how to use the claimed polynucleotides, such as: (1) the biochemical activity of the polypeptide being encoded by the claimed polynucleotides, (2) the cellular processes or pathways in which the recited protein is involved, (3) the molecular interactions associated with the recited protein, or (4) any diseases

linked to mutation/polymorphism of the recited polynucleotides and encoded proteins, such that a specific use for the claimed polynucleotides would be apparent. If information in regard to the biological role of the claimed invention were to be presented, several utilities could be apparent for the claimed polypeptide, such as purification of regulatory factors or diagnostic identification of diseases due to mutation of said protein; however, these utilities require additional information, which is not presented by the specification. As known in the art and admitted by Appellants in the specification, proteases are active in many different biological processes (pg 1, lines 25-31). Since, the cellular function of the recited protein, the biological processes associated with said protein, and any diseases due to mutation of said protein are all unknown, the utilities recited in the specification are not substantial, as they will require or constitute carrying out further research to identify or reasonably confirm a "real world" context of use. See e.g., Brenner v. Manson, 383 U.S. 519, 148 USPQ 689 (Sup. Ct. 1966). The instant situation is analogous to the lack of substantial utility examples provided by MPEP § 2107.01 in that basic research is required to study the properties of the claimed polynucleotides and the corresponding polypeptide as well as the mechanisms in which the claimed polynucleotides are involved. In addition, while one could argue that some of the recited uses are specific, such as being a probe to be used in microarrays or in mapping of nucleotides in a particular chromosome, it is noted that these uses are not specific due to the fact that, all other human polynucleotides can be used as probes in microarrays or in mapping of nucleotides in the chromosome and Appellants have not provided reasons why one of skill would be motivated to use the instant polynucleotides. Since the instant specification does not disclose a credible, specific and substantial "real world" use for the polynucleotide of SEQ ID NO: 1, or any polynucleotide encoding the polypeptide of

SEQ ID NO: 2, then the claimed invention, as disclosed, does not meet the requirements of 35 U.S.C. §101 as being useful.

Claim Rejections - 35 USC §112, first paragraph

Claims 1-6 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a substantial and specific asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

(11) Response to Argument

A. Do Claims 1-6 lack a patentable utility?

Applicants provide the following arguments, which are not found to be persuasive for the reasons discussed in each Reply.

1) The present sequence has a number of patentable utilities, among them "the identification of protein coding sequence", "identify biologically verified exon splice junctions...", and "sequences adjacent to intron/exon boundaries can be used to design primers for use in amplification assays to detect mutations...that can be used in diagnostics and pharmacogenomics". The value of biologically validated, expressed, spliced, and polyadenylated mRNA sequences is readily apparent to those skilled in the art. The present nucleotide sequence has a specific utility in mapping the protein encoding regions of chromosome 1.

Reply: While it is agreed that the claimed polynucleotides can be used in detecting the particular locus (i.e. position in the chromosome at which the gene resides) of the human genome where the gene encoding the polypeptide of SEQ ID NO: 2 is located and to map the coding

exons and the intron/exon boundaries in said locus, such uses are not considered specific for the following reasons. As known in the art, any human polynucleotide that encodes a protein can be used to detect the particular locus of the corresponding gene and to map the exons and the intron/exon boundaries within the locus. The specification fails to disclose the usefulness of said information regarding the claimed polynucleotides. For example, the specification fails to identify any intron/exon border regions that is involved in any disease or cellular process etc. As described above, each of these utilities is an application that would apply to every member of the general class of polynucleotides or is a use only for further research to determine a use for SEQ ID NO: 1, or the protein encoded thereby. As such, these asserted utilities are not specific (for those applicable to all human DNAs) or not substantial because the use of SEQ ID NO: 1, for example in diagnostics or pharmacogenomics, is only potential and not in currently available in practical form. Furthermore, all human polynucleotides can be used in mapping of nucleotides in the chromosomes and Appellants have not provided reasons why one of skill would be motivated to use the instant polynucleotides. The public is left to biologically validate the functional characteristics of the recited sequences in order to make the utilities recited in this argument "real world".

2) The Examiner seems to be confusing the requirements of a specific utility with a unique utility. The fact that a small number of other nucleotide sequences could be used to map the protein coding regions in this specific region of chromosome 1 does not mean that the use of Appellants' sequence to map the protein coding regions of chromosome 1 is not a specific utility. A requirement for a unique utility, which is improper, would preclude the Patent and Trademark Office from issuing patents on batteries, automobile tires, golf balls, golf clubs, and treatments

for a variety of human diseases. Furthermore, if each invention needed to have a unique utility, the entire class and subclass system would be an effort in futility.

Reply: Appellants have never been asked to identity a utility that is unique, i.e., not shared by any other compounds or compositions. Rather, Appellants have been required to identify a utility that is specific to the invention claimed, as opposed to one that would apply regardless of the specific properties of the claimed invention. See, e.g., Brenner, 383 U.S. at 534, 148 USPQ at 695 (An invention does not have utility sufficient to satisfy § 101 until it is "refined and developed" to the point of providing a specific benefit in currently available form.). An invention certainly can have a utility that is shared by other compound or compositions. On the other hand, not every utility will satisfy § 101, even if the utility is shared by a class of inventions. So while, a utility need not be unique to a claimed invention, it must nonetheless be specific, and in currently available form, in order to satisfy § 101. Here, Appellants state that the claimed polynucleotides can be used as in the identification of protein coding sequences within the gene, to identify biologically verified exon splice junctions, and to use sequences adjacent to intron/exon boundaries to design primers for use in amplification assays to detect mutations...that can be used in diagnostics and pharmacogenomics. However, any observed results of the identification of protein coding sequences, splice junctions, or mutations would have no meaning without additional knowledge of what the significance of the encoded protein or mutations thereof. The specification in effect discloses that the claimed polynucleotide appears to encode a protein and leaves those of skill in the art will figure out what to do with it. Said utilities are not substantial; they do not provide a specific benefit in currently available form.

3) Regarding the use of the recited polynucleotides in microarrays, Appellants point out the nucleic acid sequences are commonly used in gene chip applications without any information regarding the function of the encoded protein, or even evidence as to whether the sequence is actually expressed. Expression profiling does not require a knowledge of the function of the particular nucleic acid. Evidence of the "real world" substantial utility of the present invention is further provided by the fact that there is an entire industry established based on the use of gene sequences, or fragments thereof, in a gene chip format. Clearly the usefulness of human genomic data, such as the presetly claimed nucleic acid molecule, is substantial and credible (worth of billions of dollars and the creation of numerous companies) and well-established (the utility of human genomic information has been clearly understood for many years).

Reply: It is agreed that the use of polynucleotides in DNA chips (microarrays) is widespread and that the claimed polynucleotides can be attached to DNA chips. However, as indicated by the Examiner in previous Office Actions, for the claimed polynucleotides to be specifically useful in such application, one would require some knowledge or guidance as to the biological role of the polypeptide encoded by such polynucleotides to effectively use the information gathered in tracking the expression patterns of such polynucleotides. The reduction or increase in expression of a polynucleotide is meaningless unless one can link changes in expression with some biological function. For example, if one were to use the claimed polynucleotides in assays which would lead to the discovery of drugs of a specific condition, such as an assay which uses a DNA chip to evaluate expression patterns upon exposure to a test compound, one needs to know which diseases and/or biological functions are associated with the

expression of such polynucleotides. Otherwise, one of skill in the art would have to carry out further experimentation to determine which are the conditions (i.e. diseases) and/or biological functions associated with the claimed polynucleotides. Appellant's asserted utility of the claimed polynucleotides as specific markers which are targets for discovering drugs associated with human disease is not a specific and substantial utility since the specification is silent in regard to (1) the conditions and/or biological functions which are associated with the expression of the claimed polynucleotides, (2) whether increase or decrease in expression correlates with disease, and (3) which levels of increase or decrease in expression of the claimed polynucleotides are indicative of the presence or absence of a disease. This is analogous to the examples provided by MPEP § 2107.01 in regard to what constitutes carrying out further research to identify or reasonably confirm a "real world" context of use since, basic research is required to determine the properties or the mechanisms in which the claimed product is involved. The Examiner acknowledges the hundreds of issued patents in regard to DNA chips; however, it is noted that the instant claims are not drawn to methods of use of DNA chips or to DNA chips (microarrays) but rather to specific polynucleotides. Furthermore, the asserted use of the intant polynucleotides in DNA chips is not specific since, as Appellants have stated, many other polynucleotides including those in the public domain can and are used in DNA chips. This situation is analogous to the examples provided in MPEP § 2107.01 in regard to what constitute a non-specific utility since, as stated MPEP § 2107.01, "a specific utility is specific to the subject matter claimed. This contrasts with a general utility that would be applicable to a broad class of inventions". Therefore, in view of the lack of information as to the biological function and/or condition associated with the expression of the claimed polynucleotides, it is unclear how one of

skill in the art can reasonably conclude that the asserted use of the claimed polynucleotides in DNA chips is a specific and substantial utility.

4) A statement of utility in a specification must be accepted absent reasons why one skilled in the art would have reason to doubt the objective truth of such statement. A sequence sharing greater than 99% identity at the protein level over a large portion of the claimed sequence is present in the leading scientific repository (GenBank), and has been annotated by third party scientists wholly unaffiliated with Appellants as "Homo sapiens thrombospondin repeat containing 1 (TSRC1)" (GenBank accession number NM_019032). Furthermore, additional third party scientists wholly unaffiliated with Appellants have described the full length murine homolog of the human TSRC1 sequence, and this sequence shows an expected 74% identity and 79% similarity at the protein level over the complete length of Appellants' sequence (GenBank accession number AY158701). Given these GenBank annotations, it is clear that those skilled in the art would clearly believe that Appellants' sequence is a thrombospondin repeat containing protein, specifically the human TSCR1 sequence.

The scientists that described the murine TSRC1 report that the murine and human TSRC1 likely arose from a chromosomal inversion that interrupted an ancestral ADAMTS gene (Buchner et al, 2003). In the specification as originally filed, Appellants noted the similarity of the present sequence to "the ADAMTS family of secreted proteases", which are well known to have thrombospondin repeats. Information in Buchner et al, 2003 is completely consistent with Appellants' sequence being a splice variant of the human TSCR1 gene. The human TSCR1 sequence of Buchner et al is over 99% identical over nearly the entire sequence with SEQ ID NO: 2.

Reply: Although it is acknowledged that the polypeptide encoded by SEQ ID NO: 1, as set forth by SEQ ID NO: 2, has homology with the TSRC1 protein of Buchner et al, a utility for the recited polynucleotide cannot be deduced based on homology of SEQ ID NO: 2 to said protein of Buchner et al. The specification fails to assert that the protein of SEQ ID NO: 2 has the same utility as the protein of Buchner et al. Although the specification states that SEQ ID NO: 2 has structural similarity with ADAMTS proteases, said assertion of structural similarity is not an assertion of function. It is acknowledged that ADAMTS proteases have thrombospondin repeat domains, that the TSRC1 protein of Buchner et al has seven said domains, and that Buchner et al state that TSRC1 appears to be derived by chromosomal inversion that interrupted an ancestral ADAMTS gene (Abstract). However, TSRC1 has not been demonstrated to have the enzymatic activity of an ADAMTS protease. The specification does assert that the recited polynucleotides encode a protein with protease activity; however, TSRC1 has not been demonstrated to have any protease activity. In fact, the function or utility of the TSRC1 is unknown. Buchner et al clearly state that, other than thrombospondin repeat domains, TSRC1 does not contain any other predicted functional domains (pg 29, parg 4) and no enzymatic activity for TSRC1 has been demonstrated. It is known in the art that many different types of proteins with different functions and utilities have thrombospondin repeat domains (Adams et al, 2000). For these reasons, Appellants argument that utility for SEQ ID NO: 1 can be deduced by the fact that the encoded polypeptide of SEQ ID NO: 2 is homologous to the TSRC1 protein of Buchner et al, 2003 is not convincing.

5) The threshold of utility is not high. An invention is 'useful' under section 101 if it is capable of providing some identifiable benefit. *Juicy Whip Inc. v. Orange Bang Inc.*, 185F.3d

1364, 51USPQ2d 1700 (Fed. Cir. 1999) (citing *Brenner v. Manson*, 383 U.S. 519, 534 (1966)). Additionally, the Federal Circuit has stated that, "to violate § 101, the claimed device must be totally incapable of achieving a useful result." *Brooktree Corp. v. Advanced Micro Devices, Inc.*, 977 F.2d 1555, 1571, 24 USPQ2d 1401 (Fed. Cir. 1992), emphasis added. *Cross v. Iizuka* (753 F.2d 1040, 224 USPQ 739 (Fed. Cir. 1985); ("*Cross*") states "any utility of the claimed compounds is sufficient to satisfy 35U.S.C. § 101". The Federal Circuit recently emphatically confirmed that "anything under the sun that is made by man" is patentable (*State Street Bank & Trust Co. v. Signature Financial Group Inc.*, 149F.3d 1368, 47 USPQ2d 1596, 1600 (Fed. Cir. 1998), citing the U.S. Supreme Court's decision in *Diamond v. Chakrabany*, 447 U.S. 303, 206 USPQ 193 (U.S., 1980)).

Reply: The Examiner acknowledges the numerous cases cited by Appellants, wherein issues in regard to 35 USC § 101 were examined. It is noted however that only *Cross v. Iizuka* is considered relevant to the instant discussion since the inventions in that case are chemical compounds. In *Juicy Whip Inc. v. Orange Bang, Inc.*, the issue of utility was discussed in regard to a juice dispenser, *in Brooktree Corp. v. Advanced Micro Devices, Inc.*, the issue of utility was discussed in regard to a digital to analog conversion circuitry, and in *State Street Bank & Trust Co. v. Signature Financial Group, Inc.*, the issue of utility was discussed in regard to a business method.

In *Cross v Iizuka*, the issues which the Federal Circuit had to examined were whether the Board erred in finding that the utility disclosed in the Japanese priority application by Iizuka was sufficient to meet the practical utility requirement of 35 U.S.C. §101 and whether the Board erred in finding that the Japanese priority application contained sufficient disclosure to satisfy

the enablement, i.e., how-to-use, requirement of 35 U.S.C. § 112. The PTO, the Board of Patent Appeals and Interferences, and the Federal Circuit found that the claimed imidazole derivative compounds had practical *in vitro* utility since, in addition to the disclosure of the structure of the claimed imidazole derivative compounds, there was experimental evidence of the strong inhibition of thromboxane synthetase by these imidazole derivatives in human and bovine microsomes. Thromboxane synthetase is an enzyme which leads to the formation of thromboxane A2, which at the time the applications of Cross and Iizuka were filed, was postulated to be a causal factor in platelet aggregation which, in turn, is known to be associated with platelet thrombosis, pulmonary vasoconstriction or vasospasm, inflammation, hypertension, and collagen-induced thrombosis. In contrast, the instant application discloses the structure of the claimed polynucleotides and no biological characterization of the polypeptide encoded by the claimed polynucleotide other than to state that, based on sequence homology, it appears to be a protease. For the reasons indicated above, even if one assumes that the polypeptide encoded by the claimed polynucleotides is protease, the specification fails to provide sufficient information for one of skill in the art to know how to use the claimed invention. The specification is silent in regard to (1) the biochemical activity of the polypeptide being encoded by the claimed polynucleotides, (2) the biological processes or pathways in which the recited protein is involved, (3) the specific molecular interactions associated with the recited protein, or (4) any diseases linked to mutation of the recited polynucleotides and encoded proteins, such that a specific use for the claimed polynucleotides would be apparent. While one of skill in the art can reasonably conclude that the chemical compounds of Iizuka had a credible, specific and substantial utility, i.e. the imidazole derivative compounds inhibit an specific enzyme,

thromboxane synthetase, in human and bovine microsomes, a skilled artisan cannot reasonably conclude that the claimed polynucleotides have a specific and substantial, or even credible utility in view of the evidence presented.

6) In *In re Brana*, (34 USPQ2d 1436 (Fed. Cir. 1995), the Federal Circuit admonished the P.T.O. for confusing "the requirements under the law for obtaining a patent with the requirements for obtaining government approval to market a particular drug for human consumption". FDA approval, however, is not a prerequisite for finding a compound useful within the meaning of the patent laws.

Reply: While it is agreed that FDA approval is not a requirement for finding a compound patentably useful, it is noted that in the instant case, the utility rejection was not applied to the claimed invention because it failed to comply with government requirements to market the invention for human consumption. Instead, the utility rejection was applied due to the lack of information as to its biological function, as already discussed above.

7) Appellants are aware of the new Utility Guidelines set forth by the USPTO. However, the current rules and regulation regarding the examination of patent applications is, and always has been, the patent laws as set forth in 34 U.S.C. and the patent rules as set forth in 37 C.F.R., not the Manual of Patent Examination Procedure or particular guidelines for patent examination set forth by the USPTO. Furthermore, it is the job of the judiciary, not the USPTO, to interpret these laws and rules. Numerous patents have been issued over the years that claim nucleic acid fragments that do not comply with the Utility Guidelines. Thus, holding Appellants to a different standard of utility would be arbitrary and capricious, and, like other clear violations of due process, cannot stand.

Reply: Appellants are reminded that the Examiner must examine a patent application according to the guidelines set forth by the USPTO as well as the MPEP, since the Examiner has no authority to disregard such guidelines or to apply her own interpretation of patent law in the examination of the application. Furthermore, as set forth in the guidelines and the MPEP, the guidelines were promulgated by the PTO in accordance with all applicable case law and thus are believed to be consistent therewith. While the Examiner acknowledges the US patents referred to in their Brief, each application is examined on its own merits according to the current guidelines of examination as set forth by the USPTO and a discussion on the utility of any polynucleotide claimed in such patents would require a detailed review of the record of each individual case, which would be improper herein. Finally, Appellants are further reminded that the Examiner has no authority to comment in regard to the legality of the new Utility Guidelines or the MPEP as set forth by the USPTO.

B. Are Claims 1-6 unusable due to a lack of patentable utility?

Appellants indicate that arguments detailed in section VIII(A) of the Brief are incorporated by reference due to the fact that it has been determined by the courts that the utility requirement of Section 101 and the how to use requirement of Section 112, first paragraph, have the same basis. Appellants argue that since Claims 1-6 have been shown to have a "specific, substantial and credible utility" as indicated in section VIII(A), the present rejections under 35 USC 112, first paragraph cannot stand.

As indicated by Appellants, a rejection under § 112, first paragraph, may be affirmed on the same basis as a lack of utility rejection under § 101. *See, e.g., In re Swartz*, 56 USPQ2d 1703 (Fed. Cir. 2000); *In re Kirk*, 153 USPQ 48 (CCPA 1967).

Therefore, for reasons set forth above, Appellants arguments and exhibits have been fully and carefully considered, but are not considered sufficient to rebut the prima facie case of lack of utility and it is believed that the rejections should be sustained.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

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